JEIL MEDICAL CORPORATION
#702, Kolon Science Valley 2nd, 811
Guro-Dong, Guro-Gu, Seoul, 152-050 Korea
Tel : +82 2 850 3500 / Fax : +82 2 850 3535

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

2 May 2013

2. Submitter's Information [21 CFR807.92(a)(1)]

- Name of Sponsor: Jeil Medical Corporation
  - Address: #702, Kolon Science Valley 2nd
    811, Guro-dong, Guro-gu
    Seoul, 152-050, Korea
- Contact Name: Ji-Eun Kim (Ms.) / RA Manager
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- Registration Number: 3004049923
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: ARIX Foot System
- Common Name: Bone plates and screws
- Classification Name: Single/multiple component metallic bone fixation appliances and accessories
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 888.3030
- Product Code: HRS
- Device Class: II

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission is shown as follows:

- 510(k) Number: K063875
- Applicant: Howmedica Osteonics Corp.
- Common Name: Bone plates and screws
- Device Name: Stryker Foot Plating System

- 510(k) Number: K023360
- Applicant: Jeil Medical Corporation
- Common Name: Bone fixation plates
- Device Name: Leforte System Bone Plate

- 510(k) Number: K023365
- Applicant: Jeil Medical Corporation
- Common Name: Bone fixation screws
- Device Name: Leforte System Bone Screw

- 510(k) Number: K112457
- Applicant: Jeil Medical Corporation
- Common Name: Bone fixation Plates & Screws
- Device Name: Leforte System Bone Plate & Screw

There are no significant differences between the Model ARIX Foot System and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, and operational principles as internal fixation components.

5. Description of the Device [21 CFR 807.92(a)(4)]

The ARIX Foot System is rigid fixation consisting of plates and screws in various configurations, shapes and sizes, as follows:

	Plate	Cortical Screw	Locking Screw	Lag Screw (Cannulated Type)	Lag Screw (Cannulated Headless Type)
Type/ Configuration	F28-Series	28-FC-Series	28L-HF-Series	23-CS-Series, 30-CS-Series, 45-CS-Series, 60-CS-Series	15-CH-Series, 23-CH-Series, 30-CH-Series
	F35-Series	35-FC-Series	35L-HF-Series		
Material	ASTM F67, Unalloyed Titanium	ASTM F 136, Titanium Alloy (Ti-6Al-4V)	ASTM F 136, Titanium Alloy (Ti-6Al-4V)	ASTM F 136, Titanium Alloy (Ti-6Al-4V)	ASTM F 136, Titanium Alloy (Ti-6Al-4V)

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The ARIX Foot System is made of Unalloyed Titanium and Titanium Alloy (Ti-6AL-4V), which meet ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications, and ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known biocompatibility.

The plates vary essentially through different lengths and number of plate holes. The screws are self-tapping with various diameters, which are applied with the reconstruction locking screws together. The Cortical Screws & locking screws are provided with diameter 2.8 mm to 3.5 mm and lengths from 8 mm to 50 mm, lag screws (Cannulated and Cannulated Headless Types) with diameters of 1.5 mm to 6.0 mm and lengths of 8 mm to 80 mm.

It also includes various manual surgical instruments, such as guide pins, drill guides, drill bits and driver shafts, washers, drill sleeve, depth gauge, bender, cleaning stylet and handbody.

The ARIX Foot System not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. The sterilization method is presented in the instruction, which was validated per ISO 17665-1: 2006 Sterilization of health care products – Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

This device performance is not adversely affected by aging or storage conditions since this device is to be sterilized at the hospital before use and also to be single use.

6. Intended Use [21 CFR 807.92(a)(5)]

The ARIX Foot System is intended for use in internal fixation, reconstruction, or arthrodesis of small bones including the fore, mid- and hind foot and ankle. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

ARIX Foot System, Bone Plates: Based on a technical feature comparison, the subject device was found to be similar to all predicate devices with regard to design and materials. The subject plates also have a polyaxial locking feature, similar to the design used in the predicate device (K063875).

ARIX Foot System, Bone Screws: They share similar head, neck, and thread designs as the smaller screws that are currently cleared under the predicate device (K063875).

Non-Clinical Test Summary:

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

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- ASTM F 382-99, Standard Specification and Test Method for Metallic Bone Plates
- ASTM F 543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws

The following tests were performed with the predicate device:

- Plates
  - Tensile strength test
  - Bending strength test per ASTM F382
- Screws
  - Driving torque test per ASTM F543
  - Axial pull-out test per ASTMV F543
  - Torsion test per ASTM F543

The results of this testing indicate that the ARIX Foot System is equivalent to predicate device.

Clinical Test Summary

No clinical studies were considered necessary and performed.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate device (K063875), the ARIX Foot System presented in this submission has the same:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Biocompatibility
- Materials
- Method of sterilization and sterility assurance level

9. Conclusion [21 CFR 807.92(b)(3)]

In all respects, the ARIX Foot System is the equivalent of currently marketed devices. This device is made of the same materials and have similar dimensions and characteristics. This device is manufactured from material of the unalloyed titanium and titanium alloy that is used generally in this kind of bone plate/screw system. This device, ARIX Foot System, is substantially equivalent in design, material, and function to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Jeil Medical Corporation
Ms. Ji-Eun Kim
RA Manager
Number 702
Kolon Science Valley 2nd 811
Guro-Dong, Guro-Gu
Seoul, Republic of Korea, Korea 152-050

September 5, 2013

Re: K131311
Trade/Device Name: ARIX Foot System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: July 30, 2013
Received: August 1, 2013

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131311

Device Name: ARIX Foot System

Indications for Use:

The ARIX Foot System is intended for use in internal fixation, reconstruction, or arthrodesis of small bones including the fore, mid- and hind foot and ankle. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S